



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,632	05/31/2007	Jeffrey Sebastian	628-1002-140-US	3580
51523	7590	12/07/2010		
Louis C. Paul Louis C. Paul & Associates, PLLC 150 East 58th Street 34th Floor New York, NY 10155			EXAMINER SCHUBERG, LAURA J	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 12/07/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,632	<b>Applicant(s)</b> SEBASTIAN ET AL.	
	<b>Examiner</b> LAURA SCHUBERG	<b>Art Unit</b> 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 7-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 7-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This action is responsive to papers filed 09/17/2010.

Claims 1, 3, 7, 8, 10 and 11 have been amended. New claims 12 and 13 have been added. Claims 2 and 4-6 have been newly canceled.

Claims 1, 3, 7-13 are pending and have been examined on their merits.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1657

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1, 3, 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (US 6,372,494) in view of Xu et al (US 2002/0022268)**

Amended claim 1 is drawn to a composition for use as a topical skin care product comprising a) a conditioned embryonic stem cell culture medium in which stem cells are cultured without fibroblast feeder cells; b) a conditioned fibroblast cell culture medium; and c) a delivery vehicle adapted for topical administration.

Dependent claims are drawn to the type of cells, the form of the composition, the process by which the composition is formed, wherein the cells are genetically modified and additional active agents.

Claims 7-8 and 13 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. § 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put

Art Unit: 1657

before it and then obtain prior art products and make physical comparisons therewith.”

*In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Naughton et al describe methods of making a conditioned cell culture medium composition wherein an embodiment is used with a bandage (delivery vehicle) in topical wound healing (column 5 lines 29-45). The cells used to make the conditioned culture medium include stromal cells (specifically fibroblasts) and/or stem cells (column 9 lines 35-45). The cells are preferentially culture in a three-dimensional culture (column 10 lines 14-15). “The stromal cells used in three-dimensional culture comprise fibroblasts, mesenchymal stem cells, liver reserve cells, neural stem cells, pancreatic stem cells, and/or **embryonic stem cells** with or without additional cells and/or elements described more fully herein” (column 10 lines 17-21). The phrase “and/or” is interpreted in this sentence as suggesting that the conditioned cell culture medium can be produced by either just one of the cell types or a mixture of two or more of the listed cell types. Naughton et al also teaches wherein the cells are genetically engineered (column 17 lines 34-37) and wherein the form of the composition can be a solid, lyophilized, powder, film or gel (column 22 lines 39-65). The use of human embryonic stem cells is specifically suggested (column 9 lines 34-65). The cells may be cultured in any manner known in the art including in monolayer, beads or in three-dimensions and by any means (column 9 line 66- column 10 line 6). While a three-dimensional construct is taught as preferred (column 10 lines 14-15), it is not required and does not necessarily include a feeder-layer (column 6 lines 43-50) and therefore a feeder-layer is optional. In fact, propagation of embryonic stem cells in feeder-free systems is known in the prior art

Art Unit: 1657

as taught by Xu et al (page 3 para 31-32). Xu et al specifically teach the use of conditioned media to support the growth of human embryonic stem cells. Therefore one of ordinary skill in the art would be motivated with a reasonable expectation of success to culture embryonic stem cells in a feeder-free system as Xu et al suggest this as an alternative to feeder cell systems and Naughton et al teach that any method known in the art would be suitable as well.

The conditioned medium composition may also include added products such as antibiotics, antivirals, antifungals, steroids, analgesics, antitumor drugs, investigational drugs or any compounds which would result in a complimentary or synergistic combination with factors in the conditioned medium (column 28 lines 49-60). The addition of ascorbic acid (vitamin C) is also suggested as suitable as well (column 9 line 10). Therefore the addition of ingredients such as those claimed by Applicant in new claims 12 and 13 would have been obvious to one of ordinary skill in the art as these ingredients are all known in the prior art to provide therapeutic benefits upon administration.

While Naughton et al does not teach a specific embodiment with a combination of just embryonic stem cells and fibroblast cells, this combination is deemed to be obvious based on the suggestion by Naughton et al that the stromal cells used to form the conditioned medium can be a mixture of these cells with or without additional cells or elements (column 10 lines 17-21). This statement clearly provides motivation with a reasonable expectation of successfully producing a conditioned medium composition

Art Unit: 1657

with a combination of fibroblast conditioned media and embryonic stem cell conditioned media without additional elements or cells.

In addition, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine conditioned media compositions known to be used individually for the same purpose of the topical treatment of wounds. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846,850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore the combined teachings of Naughton et al and Xu et al render obvious Applicant's invention as claimed.

### ***Response to Arguments***

Applicant's arguments filed 09/17/2010 have been fully considered but they are not persuasive. Applicant's arguments have been addressed in so far as they relate to the new rejection above.

Applicant argues that the '494 patent (Naughton et al patent) does not teach or suggest compositions containing a combination of two separately obtained "conditioned

Art Unit: 1657

media” in the absence of any other type of cell that are useful in topical skin care products.

This is not found persuasive because Naughton et al specifically teach that their conditioned medium compositions can be produced without additional cells (column 10 lines 20-21) and can be used for wound healing applications (column 21 lines 23-25).

Applicant argues that the skilled artisan would not credit Naughton’s statements that embryonic stem cells are stromal cells.

This is not found persuasive because even if it is true that Naughton et al categorize embryonic stem cells in a manner different from others in the art does not negate the fact that Naughton et al specifically teach the suitability of using embryonic stem cell conditioned media either alone or combined with conditioned medium from other cell types. Since Naughton et al specifically list embryonic stem cells several times as a suitable cell type it is clear that they mean to include these cells in their conditioned medium composition.

Applicant argues that Naughton et al require three-dimensional cultures for the production of their conditioned medium composition. Applicant asserts that the three-dimensional culturing of two different cell types is always sequential and requires that the embryonic cells are not cultured alone.

This is not persuasive because Naughton et al do not require three-dimensional cultures for their invention. The three-dimensional cultures (with or without feeder cells) are taught as preferred, but Naughton et al clearly state that other suitable methods of culturing the cells known in the art are acceptable alternatives (column 9 line 66-

Art Unit: 1657

column 10 line 6). The teaching of Xu et al clearly demonstrates that culturing embryonic stem cells in a feeder-free system is a suitable alternative to feeder cell cultures (page 3 para 31-32).

Applicant argues that the Office appears to construe and apply the teachings of the Naughton et al patent in a mutually exclusive manner. Applicant asserts that culturing the cells separately and combining the conditioned medium as Applicant has done would eliminate the benefits and advantages described in the Naughton et al patent.

This is not found persuasive because even though the Naughton et al patent does not specifically describe an embodiment wherein the conditioned medium of different cell types are produced separately and then combined afterwards, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine conditioned media compositions known to be used individually for the same purpose of the topical treatment of wounds. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ....[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846,850, 205 USPQ 1069, 1072 (CCPA 1980).

Therefore the claims remain rejected as above.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA SCHUBERG whose telephone number is (571)272-3347. The examiner can normally be reached on Mon-Fri 8:00-4:30.

Art Unit: 1657

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura Schuberg  
Examiner  
Art Unit 1657

/Laura Schuberg/